K122329

510(k) SUMMARY

(As required by 21 CFR 807.92)

AUG 16 2012

5.1. Submitted by

Jet Soft SRL
Str. Anasttasie Panu Nr. 6
031164 Bucharest
Romania

Contact Person

Dr. Peter-M. Klews
Regulatory affairs
Phone: +49 4133 51 01 85
Fax: +49 4133 51 01 85
E-mail: peter@jetsoftware.eu

Date Initial Summary prepared

June 26th, 2012

5.2. Name of the Device

Proprietary Name: BioJet
Common / Usual name: Medical Imaging Processing Software System
Regulation Description: Picture Archiving and Communications System (21 CFR 892.2050)
Classification: Class II
Classification Product Code: System, Image Processing, Radiological
Product Code: LLZ

5.3. Substantial Equivalence

Predicate Device:

Device Name	Eigen 3D-Imaging Workstation
Manufacturer	Eigen LLC
510k Number	K081093
Decision Date	May 1st, 2008
Decision	Substantially Equivalent

5.4. Device Description and Summery of Technological Characteristics, Scientific Concepts

The BioJet software is designed to display the 2-D live video received from commercially available ultrasound machines and use this 2-D video to reconstruct a 3-D ultrasound image stack. The system has been designed to work with the clinicians' existing ultrasound machine and TRUS (TransRectal UltraSound)

probe, commercially available needles, needle guides or needle templates and needle gun combination. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 3-D image registration.

BioJet works with commercially available mechanical stepper and stablizer assemblies that holds the ultrasound probe and tracks the probe position while the physician performs a normal ultrasound imaging procedure of the subject prostate. The mechanical tracker is connected to a PC-based workstation containing a video image converter. Control of the ultrasound probe and ultrasound system is done manually by the physician, just as it would be in the absence of BioJet. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, BioJet is able to reconstruct and display a 3-D rendered surface model of the prostate and to display the live image position within the prostate.

Locations for biopsies, needles, markers, and other devices may be selected by the physician, displayed in the 3-D image stack and 3-D rendered surface model, and stored. Previously created 3-D models may be recalled and may be aligned or registered to the current live display of the prostate. The 3-D model used for co-registration may be based on another series of ultrasound images or DICOM images.

Finally, the physician may attach a commercially available biopsy needle guide to the TRUS probe and use the probe and biopsy needle to perform biopsies. Whenever the ultrasound machine is turned on by the physician, the live 2-D ultrasound image is displayed on the screen of BioJet during the biopsy. As the TRUS probe with attached needle guide or needle grid is maneuvered by the physician, the position and orientation of the probe is tracked. BioJet is able to add, display and edit plans for biopsy sites as well as an estimate of the probe position and needle trajectory relative to the 3-D image series and rendered surface model of the prostate. BioJet offers the physician additional 3 -D information for assessing prostate abnormalities, planning and implementing biopsy procedures.

The scientific concepts on which the BioJet Software is based is that organs such as the prostate can be visualized with a number of imaging modalities. All imaging modalities display the organs in a different way and deliver different information but they all display the same shape and size of the organ. Thus it is possible to co-register a a previously acquired 3-D model of a prostate to live ultrasound images acquired with a commercially available endo-rectal probe.

The BioJet Software provides two and 3 dimensional image review, manipulation, and analysis tools to assist users in planning and performing image-guided interventional procedures such as biopsies and the placement of instruments and markers. Supported imaging modalities include DICOM 3 images and 2D live video images received from commercially available ultrasound (US) machines. DICOM images are received from various commercially available imaging systems via a memory stick or a CD ROM. Live video US images are collected from the video output stream manually or triggered by a commercially available tracking stepper, i.e. a calibrated spatial positioning device. Non DICOM video images are - in contrary to DICOM images - not calibrated and must be scaled within the program based on scaling marks in the image and the known image spacing if collected manually. All know images from US devices include such scaling marks.

The contrast and brightness display of the images can be changed manually by the user. Additionally, the user can zoom and pan the images and also change the image coloration for better visibility. The images in the image stack can be interpolated by linear interpolation to allow an image display at 1 mm intervals.

This device provides the capability to overlay annotations on 2D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, imaging probes or other tracking devices. Additionally, the user can manually draw contours of structures (prostate, urethra, seminal vesicals, bladder, etc.) and regions of interest (ROI) into the images.

The 3-D image stack can be further processed to perform volume estimations based on the manually drawn organ contours or ROIs drawn by a physician. Patient information, notes, and images may be stored - unchanged - for future retrieval. In-plane length and angle measurements are available. The angle data pertains to the biopsy guidelines, biopsy cores, markers and instruments used. Thus only volume, length, and angle measurements are conducted. All images independant of the image format (JPEG, BMP, DICOM, PNG) are stored and displayed unchanged. JPEG images may have been created with lossy compression. For that reason the user is informed that JPEG images may have been created using a lossy compression. Images may not be used for diagnostic purposes.

Live 2-D ultrasound images are used for example during biopsy or placement of instruments. As the TRUS probe with the attached needle guide is maneuvered by the physician, the position and orientation of the probe is tracked manually or by an attached tracked device. The ultrasound image contains the available device trajectories that are manually match to the trajectories in the program. Thus the complete biopsy procedure is controlled by the user by observing the live ultrasound images and matching the respective trajectories.

The user may load image display test patterns into the program at any time for quality assessment using one of the allowed imaging modalities. These test patterns can be used, for example, to check the quality of image re-slicing, grayscale or color depiction, measurement precision or screen resolution and display.

All data and images are stored in the patient file for later retrieveal. Image are always stored as unchanged originals. The files are CRC checksum protected zip files. When a checksum is received or read, the device performs a CRC on the data and compares the resulting check value with the received one. If the check values do not match, then the block contains a data error. Otherwise, the data is assumed to be error-free. CRCs are specifically designed to protect against common types of errors on communication channels, where they provide assurance of the integrity of messages delivered. The zip format uses a 32-bit CRC algorithm and includes two copies of the directory structure of the respective file to provide greater protection against data loss.

5.5. Intended use

The BioJet software is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurements, and 3-D registration.

The intended use is the same as that of the predicate device mentioned in paragraph 5.3.

The BioJet Software provides two and 3 dimensional image review, manipulation, and analysis tools to assist users in planning and performing image-guided interventional procedures such as biopsies and the placement of instruments and markers. The patient population for which the device is intended are men usually age 40 and older that are suspected of having or actually have prostate disorders such as BPH, prostate cancer or other prostate problems.

5.6. Substantial Equivalence

In summary BioJet utilizes the same technological characteristic as the predicate device. Both:

- are PC based software applications that provide 2D and 3D medical image acquisition including ultrasound video image acquisition and visualization of the prostate gland
- use Windows operating systems
- allow co-registration of live ultrasound images to previously created 3-D image sets based on previously collected live ultrasound image sets or DICOM images sets
- include image enhancements such as contrast and brightness, zoom and pan capabilities
- provide patient and clinical data management features.
- deal with live ultrasound images received from commercially available imaging devices.
- use graphic overlays to define segmentations
- calibrate ultrasound video images
- run on a Windows operating system
- create a report
- allow for image measurements such as volume, length, and angle measurements
- allow multi-planar reformatting
- allow manual planning of instrument positioning including biopsy needle placement and planning
- allow the user to plan and mark the reached positions of the biopsies and instruments
- do not steer or in anyway control the positioning of the instruments used or of any treatment process what so ever
- are only intended for use on the prostate gland

The devices differ in a few features. These do not raise any safety or effectiveness concerns. These are:

- The predicte device uses a propriatary mechanical positioning device and BioJet uses a standard off the shelf mechanical positioning device
- BioJet TRUS contours cannot be automatically elastically deformed (non-rigid registration) to align with an MR image
- BioJet does not allow the recoding of video sequences
- BioJet also allows the user to mark the position of markers placed into the prostate.

It total the main differences relate to omitting automatic functions and add-ons that in our case must be done manually and to the use of a standard positioning device used for may years in therapy options such as

LDR/HDR brachytherapy instead of a specially produced device. These differences do not create any additional safety issues.

Summary of Testing and Performance data

The BioJet has been designed to comply with the applicable software standards:

- IEC 62304:2006,
- IEC 62366:2007,
- IEC 60601-1-4:1999
- ISO 14971:2007,
- DICOM (NEMA PS 3.1 - 3.18)
- ISO / IEC 15444-1:2005 + Technical Corrigendum 1:2007
- HIPAA (45 CFR Parts 160 and 164 as far as applicable)

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were used to verify system performance through verification, validation and benchmarking. Performance tests include tests on ultrasound phantoms that show that the biopsy guidelines in transverse and longitudinal section are precisely aligned with the biopsy guidelines on the ultrasound images. It was also demonstrated that the contours of the longitudinal display calculated from the transverse contour drawing fit onto the actual longitudinal contours of the phantom. Volume tests proved that the calculated volume is within an error of less than 3% equal to the volume displayed by the off the shelf commercially available ultrasound device used. The temporal resolution in visualizing the biopsy needles depends only on the video frequency of ultrasound machine used which is the standard NTSC video signal. All graphics functions are accessible in real-time, i.e. the user cannot detect any time delay.

As such BioJet is as safe and effective as the predicate device and is substantially equivalent to the predicate device.

Conclusions

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of BioJet with those of the predicate device demonstrate that BioJet is substantially equivalent to the existing product in the market today.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Jet Soft SRL
% Mr. Olaf Teichert
Responsible Third Party Official
(510)k TPR Program Manager
TUV SUD America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

AUG 16 2012

Re: K122329
Trade/Device Name: BioJet
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 9, 2010
Received: August 1, 2012

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE FORM

510(k) Number (if known):

Device Name: BioJet

Indication For Use:

The BioJet software is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurements, and 3-D registration.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k102329